

## REMARKS

In the final Office Action mailed December 14, 2004, all pending claims 1-16 were rejected. The withdrawal of the rejection of claims 1-16 under the judicially created doctrine of obviousness-type patenting is acknowledged. Reconsideration of claims 1-16 presently pending in light of the following remarks is respectfully requested.

The Specification has been amended to update patent serial numbers. This amendment does not constitute the addition of new matter.

### Rejection under 35 U.S.C. § 103(a):

The Examiner maintained the rejection of claims 1-16 under 35 U.S.C. § 103(a) as being unpatentable over Hernandez (U.S. Patent No. 6,235,795) in view of Granja (U.S. Patent No. 6,235,795) for reasons of record in the Office Action dated March 24, 2004. More specifically, the Examiner asserted that Hernandez discloses "mixtures of higher primary alcohols made from beeswax generically overlapping applicants' useful in treating ulcers and as anti-inflammatory agents as well as their production by extraction." The Examiner further asserted that Hernandez "differs from the instant invention in that micronizing and use in treating cholesterol and inflammatory disorders is not disclosed. Gamble et al., for similar mixtures of alcohols, disclose treating inflammatory and cholesterol disorders as well as ulcers." The Examiner then contends "it would have been *prima facie* obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of the cited references, to make applicants' compositions and to expect them to be useful in treating cholesterol and inflammatory disorders." This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, it is well established that the prior art relied upon must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references (*In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988); *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992)). Second, the proposed modification of the prior art must have had a reasonable expectation of success (*Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991; emphasis added)). Lastly, the prior art reference or combination of references must teach or suggest all the limitations of the claims (*In re Vaack*, 947 F.2d 488 20 USPQ2d 1438 (Fed. Cir. 1991; emphasis added)).

It is asserted that the Examiner has not met the requirements as defined above and therefore a *prima facie* case of obviousness has not been established. The present invention is directed to compositions comprising a mixture of primary alcohols of 20, 22, 24, 26, 27, 28,

30, 32 and 34 carbon atoms, and methods of using such compositions. This unique mixture of alcohols having the compositional profile as claimed in the present invention is neither taught nor suggested by the cited references, alone or in combination. Furthermore, not only has the Examiner failed to demonstrate why one skilled in the art would have been motivated to combine Hernandez and Granja, but even if such motivation had been established, the combination still would not provide the invention of claims 1-16. Accordingly, it is asserted that a *prima facie* case of obviousness has not been established, and on this basis alone, the rejection should be withdrawn.

More specifically, Hernandez discloses compositions containing "higher primary aliphatic alcohols in the range from 24 to 34 carbon atoms . . . *specifically* the ones that contain the primary alcohols of **24, 25, 28, 30, 32 and 34** carbon atoms" (column 3, lines 19-23; emphasis added). See also Tables 1-6 of Hernandez, which describe compositions specifically containing 1-tetracosanol, 1-hexacosanol, 1-octacosanol, 1-triacontanol, dotriacontanol, and 1-tetratriacontanol. Such compositions are referred to in Hernandez as "M.H.A.A.B.W." This combination of alcohols is obtained by a process that differs significantly from that used to isolate the composition of the present invention. Moreover, Hernandez does not teach or even suggest a method that allows for the isolation of primary straight chain alcohols of 20 and 22 carbons, let alone the unique mixture of straight chain alcohols in the amounts recited in claims 1-16.

Next, even if there were a motivation to combine the teachings of Hernandez with Granja as asserted by the Examiner, the combination would not teach or even suggest the compositions and methods of claims 1-16 since Granja does not teach the isolation of primary straight chain alcohols of 20 and 22 carbons. The combination of references advanced by the Examiner therefore do not teach the alcohol mixture claimed by the Applicants, as required by *In re Vaeck (supra)*.

Thus, although Hernandez and Granja broadly disclose mixtures of higher primary aliphatic alcohols containing alcohols ranging from 24-34 carbons, neither Hernandez nor Granja teach or suggest a mixture of primary aliphatic alcohols specifically comprising, *inter alia*, a **C-20** alcohol (i.e., 1-eicosanol) **and** a **C-22** alcohol (i.e., 1-docosanol) as required in the compositions of the present invention. Since the combination of Hernandez and Granja does not teach or suggest all of the elements of claims 1-16, a *prima facie* case of obviousness has not been established. In addition, not only is the incentive to combine Hernandez and

Granja lacking, but the combination of Hernandez and Granja still lacks all the elements of claims 1-16, and therefore the combination does not constitute prior art.

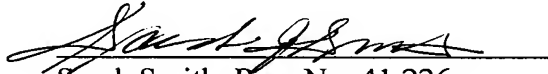
For the reasons presented above, it is asserted that claims 1-16 are clearly distinguished over the cited references, and withdrawal of the Section 103(a) rejection is respectfully requested.

### CONCLUSIONS

All of the outstanding rejections having been addressed, all pending claims are believed to be in condition for allowance, and such action is respectfully requested. The Examiner is authorized to charge any additional fees associated with the filing of this Amendment and the new claims presented herein to Deposit Account No. 50-1123. The Examiner is asked to kindly contact the undersigned by telephone should any outstanding issues remain.

Respectfully submitted,

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Dated

  
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